

### REMARKS

This submission is in response to the Office Action dated September 3, 2008. 2007. Claims 58, 60, 62-71, 89, 91-94 and 96-125 are currently rejected. Claims 58, 89, 92-93, 96, 98, 103, and 105 are amended herewith. Support can be found, for example, in paragraphs [0043], [0048], and claim 5 as originally filed. Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested. Each of the Examiner's rejections is discussed below.

#### Amendment of the Specification

The specification has been amended to incorporate patent numbers instead of the corresponding application serial numbers.

#### First Rejection under 35 U.S.C. §103

Claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114, and 117-124 have been rejected as obvious over WO 97/00076 to Morlet in view of Fox (U.S. Pat. 5,374,432) and further in view of Smith (U.S. Pat. 5,576,006). The Examiner states that Morlet and Fox teach the desirability of providing a topical antimicrobial compositions having a biguanides polymer and antimicrobial metal as claimed and further, that Fox teaches that a combination of silver with other antimicrobials provides improved antimicrobial efficacy, and Smith teaches substantially water insoluble biocidal agents.

Applicants respectfully traverse. Smith, as opposed to the Examiner's characterization, does not teach substantially water insoluble biocidal agents. While Smith does teach antimicrobial complexes that are "less water soluble and more hypoallergenic" due to the increased size of the complexes, these complexes are clearly distinguished from the present invention. As stated by Smith:

The formation of these simple but larger complexes or compounds has the effect of creating a **slower release type of functional compounds**. Therefore, a larger lasting effect is achieved with these complexes

(Smith, col. 3 lines 19 – 22, emphasis added). Thus, the antimicrobial complexes of Smith **release** the biocidal agent. Smith does not teach or suggest an antimicrobial component that is substantially water-insoluble or can be rendered substantially water-insoluble since the Smith complex **does** "dissolve, elute, leach or otherwise provide species into a liquid environment in contact with the compositions at levels that would result in solution disinfection, that is, in antimicrobially effective amounts" (see para. [0037] of the current specification). Smith teaches a slow release of the biocide from an anionic polymer matrix

that then provides a longer lasting effect that is less hypoallergenic as compared to other previously known biocides—both stated advantages are due to the **slow release** of an antimicrobially effective amount of the biocidal agent into the contacting liquid environment and not to a “handoff” of an antimicrobial component directly to the microorganism upon contact with the composition (see para. [0021] of the current specification). Thus, Smith does not teach or suggest a moisture-resistant film that imparts a persistent antimicrobial activity or a substantially water insoluble antimicrobial. Therefore, since neither Smith, Morlet, nor Fox teaches nor suggest each limitation of the presently claimed invention, the present claims are not obvious over Morlet in view of Fox and Smith.

Additionally, use of the less water soluble compositions of Smith are clearly distinguished from the use of the compositions as presently claimed, which contain a substantially water insoluble antimicrobial component that consists essentially of a antimicrobial organic cationic polymer (or more specifically a biguanide polymer), an antimicrobial metallic material, and an optional organic compound, which is substantially water-insoluble or can be rendered substantially water-insoluble, wherein the water-insolubility is facilitated by the formation of a complex of the antimicrobial polymer and the antimicrobial metallic material or formation of an adduct of the antimicrobial polymer and the organic compound. In contrast, the reduced solubility of Smith is due to the increased molecular weight of the non-biocidal anionic polymer, polycarboxylic acid. Similarly, while Morlet teaches the use of antimicrobial poly(hexamethylene biguanide) salts, Morlet does not teach or suggest an antimicrobial component that consisting essentially of an antimicrobial polymer, an antimicrobial metallic material, and an optional organic compound, which is substantially water-insoluble or can be rendered substantially water-insoluble, wherein said water-insolubility is facilitated by the formation of a complex of the antimicrobial polymer and the antimicrobial metallic material or formation of an adduct of the antimicrobial polymer and the organic compound. Thus, the combination of Morlet, Smith, and Fox does not teach or suggest every limitation of the presently claimed invention.

Applicants restate that the abstracts of Examples A – E, as discussed previously, when combined with the teachings of Fox, demonstrate that this field is unpredictable. Applicant note that the Examiner disagrees, however, the summary provided by the Examiner mischaracterizes these abstracts. According to the Examiner, Examples A and B are not commensurate in scope with Fox since they teach mixing a sodium salt with an antimicrobial whereas Fox teaches mixing silver or a silver salt with other antimicrobials. However, according to this reasoning, the presently claimed combination with biguanide antimicrobials are also not commensurate in scope with Fox since Fox teaches only the combination of silver or silver salt with a specified list of antimicrobials (see Response to Action dated April 4, 2007 for

further discussion of the Fox antimicrobials), and in fact does not teach or suggest using or combining polymeric antimicrobials at all. Based on these references, a person of ordinary skill in the art would have no more motivation or reason to consider substituting, for example, a biguanide polymer for a cephalosporin or  $\beta$ -lactam (Fox) as they would substituting, for example, a silver salt for a sodium salt (A or B).

The Examiner also states that Example D and E provide positive results. However, Example D actually shows one positive result and three results showing no statistical difference while Example E teaches that the antibacterial properties of the individual drugs were not affected by the combination of antimicrobials (i.e., having no improved antimicrobial efficacy). A person of ordinary skill in the art would have not motivation to go through the effort of combining different antimicrobial agents to improve efficacy if they had no expectation that the effort would provide any improved efficacy. Thus, the abstracts showing no statistical differences effectively teach against using a combination. Thus, Examples A - E in combination with Fox, demonstrate to a person skilled in the art that the effect of these combination is unpredictable and any improvements would have to be determined by trial and error. A person of ordinary skill in the art would look to the whole of the art in the field and would have no reason to look only at Fox at the exclusion of Examples A - E when determining what the art teaches and suggests. Thus, such a person of ordinary skill in the art would not be motivated to combine an antimicrobial metallic metal with an antimicrobial polycationic polymer as in the methods as presently claimed. Thus, the presently claimed invention is not obvious in view of Morlet as combined with Fox and Smith.

For at least these reasons, claims 58, 89, 92, 93, 96, 98, 103, and 105 and the remainder of the claims which depend there from and have each of the limitations of these dependent claims are patentable over Morlet in view of Fox and Smith. Thus, claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114, and 117-124 are not obvious over Morlet in view of Fox and/or Smith and Applicants respectfully request that this rejection be withdrawn.

#### **Second Rejection under 35 U.S.C. §103**

Claims 65-67, 91, 94, 97, 104, 107, and 115 – 116 are rejected as obvious over Morlet in view of Fox, Smith, and further in view of WO 95/17152 (the '152 publication). The Examiner contends that Smith teaches forming complexes of antimicrobial compounds that are less water soluble, and Fox teaches the combination of silver with other antimicrobials provides improved antimicrobial efficacy.

The Examiner further states that the '152 publication exemplifies an antimicrobial coating solution containing the elected species of methylene-bi(N,N-diglycidylaniline) and silver iodide.

Applicants respectfully traverse. There is nothing in the '152 publication that overcomes the deficiencies as described above for the combination of Morlet, Smith and Fox. Therefore, applicants respectfully request that the rejection under 35 U.S.C. §103 for claims 58, 60, 62-71, 89, 91-94, and 96-124 be withdrawn.

### **Double-Patenting**

All claims have been rejected by the Examiner under the judicially created doctrine of obviousness-type double-patenting as being allegedly unpatentable over various claims in commonly-owned U.S. Patents 6,180,584; 6,030,632; 5,869,072; and 5,817,325. Upon indication of allowable subject matter in the present application, the allowable subject matter not being patentably distinct from the claims of one or more of the above-cited patents, an appropriate terminal disclaimer will be timely filed.

Therefore, in view of the above remarks, it is earnestly requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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